Understanding safety differently: developing a model of resilience in the use of intravenous insulin infusions in hospital in-patients - a feasibility study protocol

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Understanding safety differently: developing a model of resilience in the use of intravenous insulin infusions in hospital in-patients—a feasibility study protocol

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ABSTRACT

Background Intravenous insulin infusions are considered the treatment of choice for critically ill patients and non-critically ill patients with persistent raised blood glucose who are unable to eat, to achieve optimal blood glucose levels. The benefits of using intravenous insulin infusions as well as the problems experienced are well described in the scientific literature. Traditional approaches for improving patient safety have focused on identifying errors, understanding their causes and designing solutions to prevent them. Such approaches do not take into account the complex nature of healthcare systems, which cannot be controlled solely by following standards. An emerging approach called Resilient Healthcare proposes that, to improve safety, it is necessary to focus on how work can be performed successfully as well as how work has failed.

Methods and analysis The study will be conducted at Oxford University Hospitals NHS Foundation Trust and will involve three phases. Phase I: explore how work is imagined by analysing intravenous insulin infusion guidelines and conducting focus group discussions with guidelines developers, managers and healthcare practitioners. Phase II: explore the interplay between how work is imagined and how work is performed using mixed methods. Quantitative data will include blood glucose levels, insulin infusion rates, number of hypoglycaemic and hyperglycaemic events from patients' electronic records. Qualitative data will include video reflexive ethnography: video recording healthcare practitioners using intravenous insulin infusions and then conducting reflexive meetings with them to discuss selected video footage. Phase III: compare findings from phase I and phase II to develop a model for using intravenous insulin infusions.

Ethics and dissemination Ethical approvals have been granted by the South Central—Oxford C Research Ethics Committee, Oxford University Hospitals NHS Foundation Trust and University of Reading. The results will be disseminated through presentations at appropriate conferences and meetings, and publications in peer-reviewed journals.

Strengths and limitations of this study

- This study will test the feasibility of using a novel combination of methods to understand the clinical work of managing intravenous insulin infusions to understand Resilient Healthcare.
- In collaboration with healthcare practitioners, this study will result in the development of practice recommendations to improve the management of patients requiring intravenous insulin infusions.
- This study will produce a model of the use of intravenous insulin infusions.
- Although there are criticisms with the use of a video approach in that it might affect the behaviour of participants, a recent review challenged this assumption and found no evidence that video recording causes significant alteration to the usual way participants behave.

INTRODUCTION

Healthcare organisations are now highly complex and staff are becoming more stressed due to rising pressures and the high risk nature of their work.[1] Globally, it is reported that about 10% of hospitalised patients experience adverse events.[1 2] Medications can present a considerable risk to patients due to their potency and the systems in which medicines are used are one of the main causes of harm and errors in healthcare. Prescribing medication is the most common intervention in healthcare and medication errors are considered to be the most preventable.[3]

Insulin is a high-risk medication that can cause significant patient harm or death when used incorrectly.[4] Although intravenous insulin is extremely effective at reducing blood glucose levels quickly for hospitalised patients, this characteristic also carries the risk of causing patient harm due to errors in how it is used. Insulin requires additional measures to ensure safe prescribing, monitoring and administration.[4 5] Based on the National Diabetes Inpatient Audit (NaDIA)

(2018),[6] four out of 10 insulin-treated inpatients experienced a medication error during their hospital stay. Inappropriate intravenous insulin infusion rates, inappropriate duration, inappropriate transfer to subcutaneous insulin and infrequent monitoring are examples of problems with the use of intravenous insulin infusions.[6]

Traditional approaches to increase safety have focused on identifying systemic weaknesses that contribute to errors, for example, through incident reporting,[7] audit[8] and complaints.[9] These initiatives then result in solutions to prevent future recurrence. Common solutions have included double checking,[10] standardisation of intravenous insulin infusion guidelines and education and training of healthcare staff.[11] Such approaches do not always take into account the complex nature of healthcare systems, which cannot be controlled solely by standards or procedures. Yet, major investments to enhance patient safety have focused on these and have not resulted in convincing reductions in risk, error, harm or death due to incidents.[12]

This disappointing track record of safety improvement informed by traditional approaches has led to a call for a change in thinking about safety. An emerging approach called Resilient Healthcare proposes that although it is necessary to understand what goes wrong, there is also value and lessons to be learnt from what goes right.[13]

BACKGROUND

Resilient Healthcare is defined as 'the ability of the healthcare organisation to adjust its functioning prior to, during, or following events and thereby sustain required operations under both expected and unexpected conditions'.[13] It proposes that the complexity and variability in the healthcare environment is key to understanding how errors occur.[13] This approach considers healthcare practice not as a problem to be solved or requiring standardisation. Instead, existing practices are 'assets' because they show an organisation's ability to adapt to changing situations.[13–16]

Capturing the dynamic nature of complex work is a methodological challenge. Previous research has focused on assessing resilience in healthcare settings and implementing resilience engineering for healthcare quality improvement.[17–22] Researchers compared how work is proposed to be done (Work-As-Imagined (WAI))—that is what people say, think or assume they do—with how work is actually done by healthcare practitioners (Work-As-Done (WAD))—that is what people actually do in practice. The core concept of Resilient Healthcare directs attention to the importance of studying how work is actually done in practice because clinical work does not unfold according to prespecified policies and guidelines.[13]

There is currently limited information on how intravenous insulin infusions are used in hospitals. Additionally, although current methods for studying WAI and WAD have been documented, there are limitations to these. For example, methods to understand WAI include the analysis of documents, reports and protocols.[17 19] WAI is not limited to what is written in a document and can include professionals' perceptions and expectations of work.[23] Methods to understand WAD include field observation, interviews and focus groups[17 19 21 22] but these rely primarily on the researchers' view or lens of how work is performed and poses a risk of researcher bias.

In this study, WAI will be explored using two approaches: (1) analysing intravenous insulin infusion guidelines and (2) analysing transcripts of focus group discussions with guideline developers, managers and healthcare practitioners.

A relatively new methodology called video reflexive ethnography (VRE),[24] whereby healthcare practitioners can review and reflect on their in-situ practices, will be used to understand the interplay between WAI and WAD. As the core concept of Resilient Healthcare is to understand how work is actually done in practice and to understand how adaptations and adjustments are created and how outcomes emerge from the interplay of misalignments between WAI and WAD, video observations will show how people address their own and others' habituated activities as well as their interpretations of policies and guidelines. Video footage of real-time practices will be shown back to participants in reflexive meeting sessions where they collectively make sense of their work and negotiate meaningful, context-appropriate ways of understanding practice and enhancing work.[24–28] The collaboration between researcher and healthcare practitioners in the reflexive sessions will result in the development of workable and realistic recommendations and solutions to increase resilience in the use of intravenous insulin infusions.

Aim and objectives

The overall aim of the research is to test the feasibility of methods to understand the clinical work of managing intravenous insulin infusions to understand Resilient Healthcare.

Objectives

1. To describe and compare WAI and WAD in the use of intravenous insulin infusions in adult inpatients.
2. To understand how approximate adjustments and adaptations are made in relation to the use of insulin infusions.
3. To develop a model of the use of intravenous insulin infusions in adult inpatients.

METHODS

Setting

The study will be conducted at a single site—the Vascular Surgery Unit at the Oxford University Hospitals (OUH) NHS Foundation Trust.

Study design

This feasibility study will take place from December 2018 to December 2019 and will involve three phases (see figure 1).

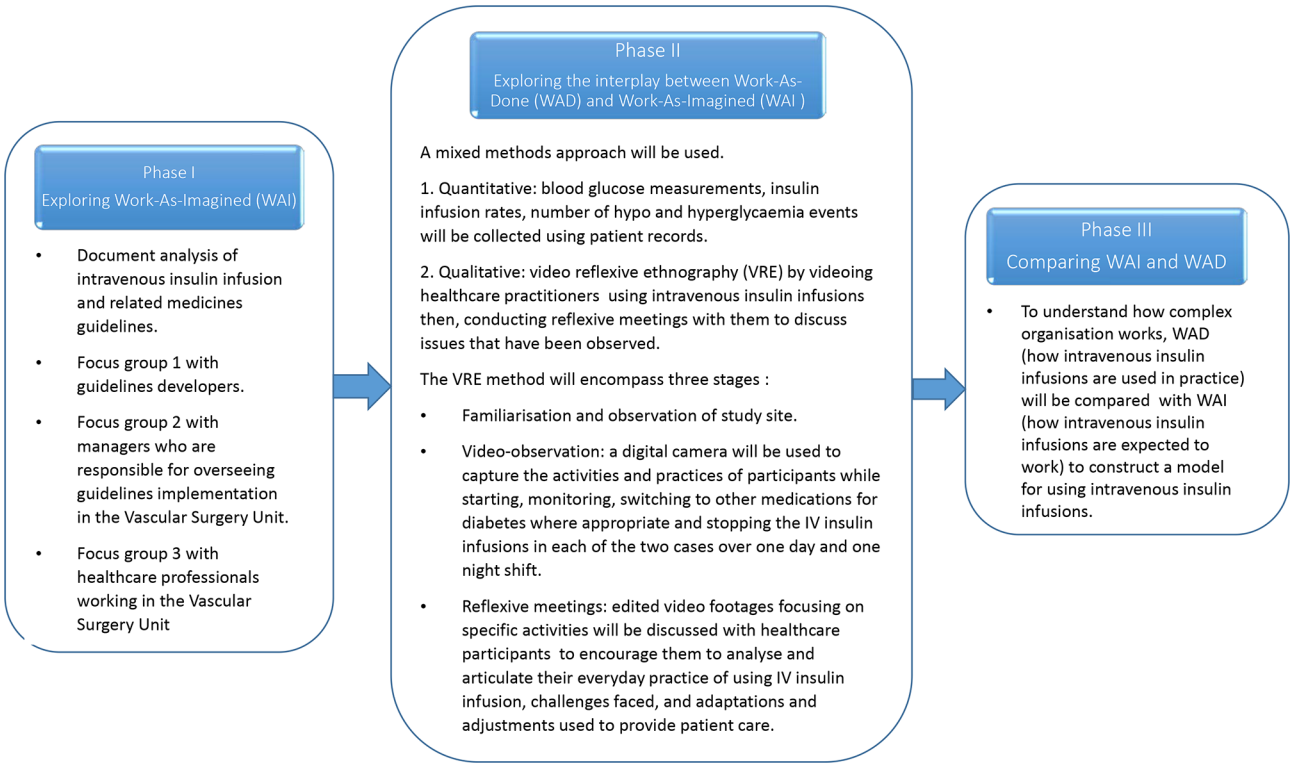

Figure 1 Flowchart of outlined study.

Phase I: exploring WAI

Phase I will consist of (1) document analysis of guidelines for the use of intravenous insulin infusions and (2) focus groups with guidelines developers, managers and healthcare practitioners.

1. Document analysis

To develop understanding and discover insights relevant to what is expected when using intravenous insulin infusions, hierarchical task analysis[29 30] will be used to analyse the documents as outlined below:

- Define the task under analysis—which is the use of intravenous insulin infusions in hospitalised patients for glycaemic control.
- Collect intravenous insulin guidelines and all related documents.
- Determine the overall goal—which is treating elevated blood glucose in hospitalised patients.
- Determine the subgoals that are required to achieve the overall goal. An inductive thematic analysis[31 32] of the intravenous insulin infusion guidelines and related documents will be conducted to identify subgoals such as indications, prescribing, administration, monitoring, adjusting infusion rates and transition to other medication for diabetes where appropriate.
- Deconstruct subgoals: each subgoal will be broken down to further subgoals and operations.
- Analyse the plans (steps) required to achieve each goal.

2. Focus groups

Sample

Three different groups of participants will be invited to take part in separate focus groups. A purposive sample of guidelines developers (five participants), managers (five to seven participants) and healthcare practitioners working at Vascular Surgery Unit (five to seven participants) will be recruited. The inclusion and exclusion criteria for participants are presented in box 1.

Box 1 Eligibility criteria for phase I focus group participants

Inclusion criteria

- Guideline developers responsible for developing and implementing local guidelines in Oxford University Hospitals (OUH) on the use of intravenous insulin infusions.
- Managers responsible for controlling resources and staffing and overseeing the implementation of intravenous insulin infusion guidelines in the Vascular Surgery Unit.
- Healthcare practitioners without a management role who care for patients requiring intravenous insulin infusions in the Vascular Surgery Unit.

Exclusion criteria

- Any participant not willing to be audiorecorded.
- Any healthcare practitioners not working in the Vascular Surgery Unit at OUH.
- Guidelines developers other than the Adult Inpatient Diabetes Specialist Team.

Recruitment and informed consent

An email invitation letter and participant information sheet outlining the purpose of the study will be sent to potential focus group participants. On the day of the focus group, signed informed consent will be obtained.

Data collection

A focus group guide, informed by hospital guidelines, policies and protocols related to the use of intravenous insulin infusions will be used throughout the discussion (online supplementary Appendix 1). A case study will be presented in the last 10 min of the session aimed to contextualise ways of working within a plausible patient case.

The discussions with healthcare practitioners will be essential to establish relationships with the researchers because they are potential participants for phase II of the study in which work practices in-situ will be observed.

The three focus group discussions will enable comparison between WAI as described by the healthcare practitioners who are in direct contact with the patients and the guideline developers and managers who have limited direct patient contact. To the best of our knowledge, this will be the first study that compares the understanding of WAI between guideline developers and healthcare practitioners.

Focus groups will be audiorecorded and audiorecordings transcribed verbatim. Any identifying information will be removed from the focus group transcripts.

Data analysis

An inductive thematic approach will be used with the aid of NVivo 12, a qualitative data management software.[33]

Phase II: exploring the interplay between WAD and WAI

Phase II will include analysis of patients' records, video observation of WAD and reflexive analysis of the recordings with participating healthcare practitioners. The inclusion and exclusion criteria for participants are presented in box 2.

A mixed-methods approach using qualitative and quantitative methods will be used.

1. Qualitative approach: VRE

This phase will use an innovative method, VRE[24] that has not been applied before in this study setting. As such, this study will test the feasibility of using the VRE method along with quantitative methods to understand how healthcare practitioners work and interact as part of a system while using intravenous insulin infusion. VRE is a qualitative research methodology that depends on collaboration between the researcher and the participant to film specific work performed by the participant.

The aim of using VRE is to improve healthcare delivery from the bottom up (WAD in practice) by directly involving healthcare practitioners in collaboration with the researcher in understanding the complexity of healthcare delivery.

Box 2 Eligibility criteria for phase II participants

Healthcare practitioners

Inclusion criteria
- Willing to be observed by video recording.
- Working in the Vascular Surgery Unit at Oxford University Hospitals.
- Managing patients on intravenous insulin infusions.

Exclusion criteria
- Not involved in the use of intravenous insulin infusions.

Patients

Inclusion criteria
- Aged ≥18 years old.
- Receiving intravenous insulin infusion for at least 24 hours to treat hyperglycaemia.
- Under the care of healthcare practitioners who have consented to participate in this study.
- Able to provide informed consent.

Exclusion criteria
- Not willing to be observed by video recording.
- Not prescribed intravenous insulin infusions.
- On intravenous insulin infusion to treat hyperkalaemia
- Non-English speakers.

A key concern with using video approaches is the effect of videoing on the practices and communications between the participants and the patients. A recent review found no evidence that video recording causes significant alteration to the usual way participants behave.[34] However, there is a possibility that changes to working practices may occur at the initial stages of video recording. To address this, the researcher will familiarise herself with the workflow of participants in the wards, she will observe and consult with participants about where she should best 'locate' herself during videoing. The researcher will ensure video recording is not intrusive to the daily routines of participants and will stop recording if appropriate for example, medical emergency.

Sample

In this feasibility study, two patient cases receiving intravenous insulin infusion will be observed to provide a clear understanding of actions and tasks that should be performed while managing patients on intravenous insulin infusion. The sample size of two cases was determined by time and resource constraints and Uncertanties about the quantity and quality of the data to analyse.

Recruitment and informed consent

Healthcare practitioners:

Three different ways will be used to recruit potential participants:

1. The researcher will join various existing meeting(s) to meet as many healthcare providers working in the Vascular Surgery Unit as possible, and to explain the VRE study.
2. A poster with details about the study will be placed in the staff room and on the door of the toilets until the completion of data collection for phase II.

3. An invitation letter and participant information sheet outlining the purpose of the study, the methodology and the design will be sent to all potential participants working in the Vascular Surgery Unit.

On the day of the videoing and prior to switching on the camera, informed consent will be obtained for observing the participant while using intravenous insulin infusion by video recording and participating in video reflexive meetings. In cases where the researcher is unable to obtain written consent before videoing, verbal consent will be obtained, and written consent sought as soon as possible afterward (posthoc consent).

Patients

The patient will be provided with an invitation letter and participant information sheet to explain the purpose and objectives of the study, which includes videorecording and the use of medical records. The patient will be given time to ask any questions about the study before giving written informed consent. To ensure that patients do not feel obliged to participate, we have included information in the participant information sheet and consent form that participation is entirely voluntary. The patient will also have information, in the participant information sheet, about their right to withdraw, how to withdraw and what will happen to any study data collected. Prior to taking informed consent, the researcher will also verbally explain the voluntary nature of participation and their right to withdraw from the study. Files with participant's identifiers (videos and quantitative data) will be immediately deleted if a participant decides to withdraw from the study.

Data collection

Data will be collected in three stages:

Stage 1: familiarisation and observation of study site

The researcher will familiarise herself with the healthcare environment in the Vascular Surgery Unit by initially using data from focus group 3 (phase 1) to identify key areas of practice using intravenous insulin infusion to focus on during the video observation stage. Then, the researcher will familiarise herself with the environment by finding areas other than the bed space to be videoed such as the treatment room where infusions are stocked and the electronic patient records are completed. The researcher will also speak informally with staff working in the Vascular Surgery Unit; conduct two general observations of the use of intravenous insulin infusions and record the observation in a notebook. These observations will be conducted for short periods of 30–60 min during normal working hours (day shift) and night shift.

Familiarisation will be accomplished by observing actual work practices and by reviewing the electronic patient record for historical usage of intravenous insulin infusions.

Stage 2: video-observation

A digital video camera will be used, and another one will be available on site as a backup camera in the event of technical failures. The researcher will video the activities and practices of participants while starting, monitoring, switching to other medications for diabetes and stopping the intravenous insulin infusions. Each case will be observed over 24 hours (one day shift and one night shift). The research team will review the video footage collected and mask all identifiers using a video cartooniser software (Adobe Premiere Pro) that turns videos to cartoons. To reduce any potential bias, the research team consisting of those with different expertise and roles will select 3–4 short video clips of interest lasting around 1.5–3 min for use in the reflexive meeting. Clips of interest might include set-up of intravenous insulin infusions, treatment decisions to increase/decrease infusion rates and to stop intravenous insulin infusion and any additional unique aspects of the use of intravenous insulin infusion observed by the researcher.

Stage 3: reflexive meeting

Each participant will attend one arranged small group reflexive meeting to allow them to watch selected video footage, explore issues identified in observations and propose different solutions and recommendations to enhance patient safety in the use of intravenous insulin infusions. The researcher will be in the reflexive meeting discussions to facilitate the discussion, to indicate some issues identified through video observation, to prompt questions and to elicit innovations (online supplementary Appendix 2).

All reflexive meetings will be held in a private room in the OUH for 30–60 min and will be audiorecorded and then transcribed verbatim. The transcripts will provide the researchers with an essential record of the discussions and the potential solutions and plans provided by the participants.

Analysis

Non-identifiable codes will be used to refer to the participants in the written materials. An inductive thematic approach will be used with the aid of NVivo 12 to analyse the recordings of the reflexive meetings. Initial themes derived from the analysis of data will be discussed within the wider research team. Master themes will be developed following identification of cross-cutting patterns and themes within and across the data from the video reflexive meetings.

To ensure trustworthiness, two members of the research team will independently code transcripts and differences in interpretation will be resolved through discussion between coders.

2. Quantitative approach: analysis of patients' records

Electronic patient records of two patients whose care will be observed through VRE will be accessed retrospectively after videoing, to identify extra relevant quantitative data

covering the 24 hours of recording such as blood glucose measurements, and infusion rates, and monitoring frequency for the intravenous insulin infusion.

Analysis

Descriptive statistics (actual numbers and percentages) will be used to compare blood glucose, infusion rates and monitoring frequency for intravenous insulin infusion against the hospital's standard protocols.

From the data, the number of hyperglycaemic (>12.0 mmol/L) and hypoglycaemic (<4.0 mmol/L) events, the cumulative time that the insulin infusions were held for hypoglycaemia, and the number of times that the patient required an intravenous 'rescue' 20% glucose infusion to treat hypoglycaemia will be calculated to determine the efficiency and safety of using intravenous insulin infusions.[35 36]

The quantitative data are complementary to the qualitative as it is an objective measure of WAD and qualitative data from VRE will provide context and meaning of the measured data in patients' records.

Data storage and security

All storage of data will adhere to the General Data Protection Regulation 2016 and the Data Protection Act 2018. Participant identifiable data will be stored on a password-protected project shared drive. The final study data set (focus group and reflexive meeting discussion transcripts' with non-identifiable codes and cartoonised videos for the video observation stage) and data that directly underpins the research findings will be stored on the University of Reading Research Data Archive.

Phase III: developing a model for using intravenous insulin infusions

A comparison of discursive descriptions of findings from phase I and phase II will be performed to produce a model showing concepts that represent misalignments between WAI and WAD. Findings will be analysed and interpreted within the context of Resilient Healthcare theories. The model will be supplemented by summaries of underpinning data used to identify and categorise misalignments, and the outcome of work performed. We will interpret the outcome of work by comparing descriptions by healthcare practitioners in the reflexive meetings against quantitative data from patient records.

Developing a systems model based on our study data brings together disparate sources of information to provide an evidence-base for future intelligent redesign of the system. The model will provide a systems view of how intravenous insulin infusions are used; highlighting and providing nuanced insight into interactions between and among key parts of the system such as people, tasks, technology and environment, that can influence processes and outcomes, to explain how mismatches between WAI and WAD occur.

Patient and public involvement

Patients will be actively involved in the dissemination of the study findings through interactive workshops with patient representatives, healthcare providers and policy-makers to influence attitudes and behaviours surrounding the use of intravenous insulin infusions within hospitals.

DISCUSSION

This study is designed to evaluate the feasibility of methods to understand the clinical work of managing intravenous insulin infusions and functionality of constructing a model of the use of intravenous insulin infusion using a Resilient Healthcare approach. Although many research studies have focused on the use of Resilient Healthcare to improve safety by comparing WAI with WAD,[17 19 21 22] no study to date has examined and strengthened resilience in the use of specific medications such as intravenous insulin infusions.

To understand WAD, interviews and focus groups have been used in previous qualitative research to improve quality of care and resilience in an emergency department[17 19] clinical handovers[21 37] and inpatient diabetes care.[22] The assumption that participant's words are reliable indicators of what happens in actual practice may be questionable. Interviews and focus groups, usually convened by the researcher, focus on a particular issue or problem. Interviewees may choose to withhold certain information or change it, particularly if the 'truth' is inconsistent with their preferred self-image.[38] Focus group data are the product of context-dependent group interactions, and participants might or might not disclose certain information during the focus group discussion.[39] Observational research establishes what people actually do or say, rather than what they say they do. Observations can, however, include a degree of researcher bias as the method relies on the interpretation of observations. The researcher cannot 'see' attitudes and memories and so it can be difficult to create an accurate analysis from observation alone. To overcome problems using these approaches in understanding WAD and describing the complexity of healthcare, VRE will be used to capture how work with intravenous insulin infusion is actually done, what complexities healthcare practitioners encounter, what creative adaptations are made, and how they deal with expected and unexpected conditions. As a form of reasoning, reflexive discussions with healthcare practitioners will draw attention to aspects that remained taken for granted before witnessed on video, but which are critical in understanding why work was done in such ways. This will allow healthcare practitioners to think of ways to reshape their practices to improve their work and patient safety.

CONCLUSION

This study will test the feasibility of a mixed-methods approach designed to explore and strengthen resilience

in the use of intravenous insulin infusions by comparing WAI from different perspectives (guideline developers, managers and healthcare practitioners alongside analysing intravenous insulin infusion guidelines) with WAD. It will explore and develop understanding of the actual work in the use of intravenous insulin infusion through videoing practices and then discussing the resultant footage with the healthcare practitioners to identify how they do their work. This way of understanding resilience in healthcare will introduce different views on what actually happens in the use of an intravenous insulin infusion. It will help in understanding why and when there are misalignments between WAI and WAD, what creative adaptations may be performed to overcome misalignments and assist in the development of a model for the use of intravenous insulin infusion in hospitalised in-patients.

DISSEMINATION

There are different key audiences for this research, including healthcare practitioners, patients and the public, the Joint British Diabetes Societies for Inpatient Care Group (JBDS-IP), The Getting It Right First Time (GIRFT) Programme, developers of diabetes guidelines at OUH, Diabetes UK and academia. The findings of the study including recommendations, solutions to enhance the safety in the use of intravenous insulin infusions and the model for intravenous insulin infusion use will be presented to healthcare practitioners, guideline developers and managers at the study site. In addition, presentations will be given at national and international conferences and seminars, and workshops with patients' representatives. Findings will be published in peer-reviewed journals. Participants and interested parties can request a copy of the Final Study Report. Findings will be of interest to those involved in safety and resilience of intravenous insulin infusions such as the Patient Safety Team NHS Improvement, GIRFT and JBDS-IP.

Contributors RL and CC conceived the idea for the study. MHI, RL, KR and CC collaborated in designing the study. The manuscript was first drafted by MHI. The statistical advice was provided by RL, KR and CC. MHI, RL, KR, CC and RI contributed to the critical revision of the manuscript. RI contributed to the methodology advice on VRE. All authors read and approved the final manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval Ethical approval for the study has been granted by the South Central—Oxford C Research Ethics Committee (REC reference 18/SC/0456), Oxford University Hospitals NHS Foundation Trust Research and Development department (REC reference18/SC/0456) and University of Reading's Research Ethics Committee (UREC 18/03).

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